

PATENT

ATTORNEY DOCKET NO. 59046.000043  
(FORMERLY ENZ-64(D2))

\$ DAC  
TFW

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Application Number : 10/733,686 Confirmation No. 9035  
Applicant : Yaron ILAN, et al.  
Filed : December 10, 2003  
Title : REGULATION OF IMMUNE RESPONSES BY MANIPULATION  
OF INTERMEDIARY METABOLITE LEVELS  
TC/Art Unit : 1648  
Examiner: : Emily M. Le  
Docket No. : 59046.000043 (Formerly Enz-64(D2))  
Customer No. : 21967

**PETITION FOR REVIVAL OF AN APPLICATION FOR PATENT  
ABANDONED UNINTENTIONALLY UNDER 37 C.F.R. § 1.137(b)**

**Mail Stop Petition**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Sir:

The above-identified application (the "Application") became abandoned for failure to file a timely and proper reply to the Office Action Election/Restriction, mailed on October 6, 2004, by the United States Patent and Trademark Office.

Applicants respectfully petition for revival of the Application. In order to obtain a grantable petition, Applicants are submitting the required items listed below:

- 1) PETITION FEE in the amount of \$750.00 as set forth under 37 C.F.R. § 1.17(m);
- 2) A REPLY: The enclosed Response to Restriction Requirement provides a complete response to the outstanding non-final Office Action mailed on October 6, 2004;

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- 3) STATEMENT: The entire delay in filing the required reply from the due date for the required reply until the filing of a grantable petition under 37 C.F.R. § 1.137(b) was unintentional.

In addition, Applicants have enclosed copies of the Office Action dated October 6, 2004; and Notice of Abandonment Under 37 C.F.R. § 1.53(f) or (g), dated June 29, 2005.

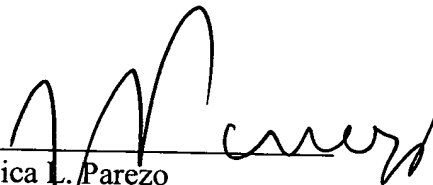
The Commissioner is hereby authorized to charge payment of any additional filing fees required under 37 CFR § 1.16 and § 1.17 associated with this communication or credit any overpayment to the deposit account of Hunton & Williams, Deposit Account Number 50-0206.

Respectfully submitted,

Date:

8/2/05

By:

  
Jessica L. Parezo  
Registration No. 50,286

Christopher J. Nichols, Ph.D.  
Registration No. 55,984

HUNTON & WILLIAMS LLP  
Intellectual Property Department  
1900 K Street, N.W.  
Suite 1200  
Washington, D.C. 20006  
(202) 955-1500 (telephone)  
(202) 778-2201 (facsimile)

JLP/CJN:cdh



# UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/733,686	12/10/2003	Yaron Ilan	Enz-64(D2)	9035

28171 7590 06/29/2005  
ENZO BIOCHEM, INC.  
527 MADISON AVENUE (9TH FLOOR)  
NEW YORK, NY 10022

EXAMINER

LE, EMILY M

ART UNIT PAPER NUMBER

1648

DATE MAILED: 06/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.



# Notice of Abandonment

Application No.

10/733,686

Examiner

Emily Le

Applicant(s)

ILAN ET AL.

Art Unit

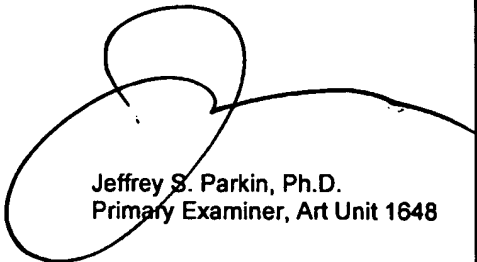
1648

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address—

This application is abandoned in view of:

1. ☒ Applicant's failure to timely file a proper reply to the Office letter mailed on 10/06/2004.
  - (a) ☐ A reply was received on \_\_\_\_\_ (with a Certificate of Mailing or Transmission dated \_\_\_\_\_), which is after the expiration of the period for reply (including a total extension of time of \_\_\_\_\_ month(s)) which expired on \_\_\_\_\_.
  - (b) ☐ A proposed reply was received on \_\_\_\_\_, but it does not constitute a proper reply under 37 CFR 1.113 (a) to the final rejection.  
(A proper reply under 37 CFR 1.113 to a final rejection consists only of: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114).
  - (c) ☐ A reply was received on \_\_\_\_\_ but it does not constitute a proper reply, or a bona fide attempt at a proper reply, to the non-final rejection. See 37 CFR 1.85(a) and 1.111. (See explanation in box 7 below).
  - (d) ☒ No reply has been received.
2. ☐ Applicant's failure to timely pay the required issue fee and publication fee, if applicable, within the statutory period of three months from the mailing date of the Notice of Allowance (PTOL-85).
  - (a) ☐ The issue fee and publication fee, if applicable, was received on \_\_\_\_\_ (with a Certificate of Mailing or Transmission dated \_\_\_\_\_), which is after the expiration of the statutory period for payment of the issue fee (and publication fee) set in the Notice of Allowance (PTOL-85).
  - (b) ☐ The submitted fee of \$\_\_\_\_\_ is insufficient. A balance of \$\_\_\_\_\_ is due.  
The issue fee required by 37 CFR 1.18 is \$\_\_\_\_\_. The publication fee, if required by 37 CFR 1.18(d), is \$\_\_\_\_\_.
  - (c) ☐ The issue fee and publication fee, if applicable, has not been received.
3. ☐ Applicant's failure to timely file corrected drawings as required by, and within the three-month period set in, the Notice of Allowability (PTO-37).
  - (a) ☐ Proposed corrected drawings were received on \_\_\_\_\_ (with a Certificate of Mailing or Transmission dated \_\_\_\_\_), which is after the expiration of the period for reply.
  - (b) ☐ No corrected drawings have been received.
4. ☐ The letter of express abandonment which is signed by the attorney or agent of record, the assignee of the entire interest, or all of the applicants.
5. ☐ The letter of express abandonment which is signed by an attorney or agent (acting in a representative capacity under 37 CFR 1.34(a)) upon the filing of a continuing application.
6. ☐ The decision by the Board of Patent Appeals and Interference rendered on \_\_\_\_\_ and because the period for seeking court review of the decision has expired and there are no allowed claims.
7. ☐ The reason(s) below:

  
E. Le

  
Jeffrey S. Parkin, Ph.D.  
Primary Examiner, Art Unit 1648

Petitions to revive under 37 CFR 1.137(a) or (b), or requests to withdraw the holding of abandonment under 37 CFR 1.181, should be promptly filed to minimize any negative effects on patent term.



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AUG 02 2005

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10/733,686	12/10/2003	Yaron Ilan	Enz-64(D2)	9035

28171 7590 10/06/2004

ENZO BIOCHEM, INC.  
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EXAMINER

LE, EMILY M

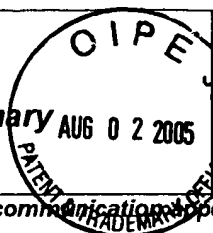
ART UNIT

PAPER NUMBER

1648

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/733,686

Applicant(s)

ILAN ET AL.

Examiner

Emily Le

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-62 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-62 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-24, drawn to a process for treating a disease in a mammalian subject comprising administering to said subject an effective amount of a mammalian intermediary metabolite or a reagent, classified in class 424 or 514, subclass-indeterminate because of functionality defined substance.
  - II. Claims 25-49, drawn to a process for treating a disease in a mammalian subject comprising obtaining cells from said subject, treating said cell with an effective amount of a mammalian intermediary metabolite or a reagent so as to raise the intracellular level of said metabolite in said cells, and transferring said treated cells to said subject; classified in class 435, subclass 325.
  - III. Claims 50-62, drawn to a process for treating a disease in a mammalian subject comprising administering to said subject an effective amount of a mammalian metabolite so as to modulate or change at least one component in the immune system of said subject, classified in class 424 or 514, subclass-indeterminate because of functionality defined substance.
2. The inventions are distinct, each from the other because of the following reasons:

Inventions I-III are independent inventions and thus are subject to restriction. The inventions are independent processes in that the methods are not dependent on each other, not disclosed as to be used together and have different functions, modes of operation or effects.

The inventions of Group I is independent from Group II. The invention of Group I does not depend on the invention of Group II, not disclosed as useable together, and have different modes of operation. The invention of Group I require the active method step of administration of either a mammalian intermediary metabolite or a reagent; whereas, the invention of Group II require the active method steps of obtaining cells from said subject, treating said cell with an effective amount of a mammalian intermediary metabolite so as to raise the intracellular level of said metabolite in said cells, and transferring said treated cells to said subject. Therefore, the invention of Group I is independent from the inventions of Group II.

The inventions of Groups I-II are independent from Group III. The inventions of Groups I-II do not depend on the invention of Group III, not disclosed as useable together, and have different functions. The invention of Group III is directed at modulating or changing at least one component in the immune system; whereas, the inventions of Groups I-II is not directed at modulating or changing at least one component in the immune system. Therefore, the invention of Group III is independent from the inventions of Groups I-II.

3. If Applicant elects Group I or II, Applicant must further elect either an intermediary metabolite or a reagent. The Examiner attempted to seek clarification on the similarity between an intermediary metabolite and a reagent by reviewing the specification. However, such clarification is not provided by the disclosure. Thus, the instant requirement is based on the assumption that a reagent is a composition that is structurally different from that of an intermediary metabolite, thereby rendering an intermediary metabolite patentably distinct from that of a reagent.



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If Applicant elects Group I, Applicant must further elect:

a) the type of disease: cancer, viral infection, bacterial infection, or immune dysfunction. If Applicant elects viral infection, Applicant must further elect HBV, HCV, or HIV. If Applicant elects immune dysfunction, Applicant must further elect diabetes type I, diabetes type II, rheumatoid arthritis, Crohn's disease, Arteriosclerosis, or ulcerative colitis. Each of the listed diseases is patentably distinct from one another. HIV is different from diabetes type II. Additionally, a search for all the listed populations would impose a serious burden on the Examiner. A search for a population that is diagnosed with rheumatoid arthritis would not overlap with a population that is diagnosed with HIV.

b) the composition of the intermediary metabolite: lipids or conjugated biomolecules. Lipids do not have a common utility with conjugated biomolecules nor do lipids have a significant structural similarity as conjugated biomolecules. Hence, lipids are patentably distinct from conjugated biomolecules.

c) the immune stimulating effect achieved by the practice of the claimed method: raising the intracellular, extracellular, or serum level of the metabolite. Each of these listed biological activities is patentably distinct from one another. An increase in the serum level of the metabolite is different from an increase in the intracellular and extracellular level of the metabolite.

If Applicant elects Group II, Applicant must further elect:

a) the type of disease: cancer, viral infection, bacterial infection, or immune dysfunction. If Applicant elects viral infection, Applicant must further elect HBV, HCV, or HIV. If Applicant elects immune dysfunction, Applicant must further elect diabetes type I, diabetes type II, rheumatoid arthritis, Crohn's disease, Arteriosclerosis, or ulcerative colitis.

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Each of the listed diseases is patentably distinct from one another. HIV is different from diabetes type II. Additionally, a search for all the listed populations would impose a serious burden on the Examiner. A search for a population that is diagnosed with rheumatoid arthritis would not overlap with a population that is diagnosed with HIV.

b) the composition of the intermediary metabolite: lipids or conjugated biomolecules.

Lipids do not have a common utility with conjugated biomolecules nor do lipids have a significant structural similarity as conjugated biomolecules. Hence, lipids are patentably distinct from conjugated biomolecules.

c) the immune stimulating effect achieved by the practice of the claimed method:

raising the intracellular, extracellular, or serum level of the metabolite; increases the rate of production of said mammalian intermediary metabolite; or decreases the rate of degradation or turnover of said mammalian intermediary metabolite. Each of these listed biological activities is patentably distinct from one another. An increase in the serum level of the metabolite is different from an increase in the intracellular and extracellular level of the metabolite or decreases the rate of degradation or turnover of said mammalian intermediary metabolite.

If Applicant elects Group III, Applicant must further elect:

a) the type of disease: cancer, viral infection, bacterial infection, or immune dysfunction. If Applicant elects viral infection, Applicant must further elect HBV, HCV, or HIV. If Applicant elects immune dysfunction, Applicant must further elect diabetes type I, diabetes type II, rheumatoid arthritis, Crohn's disease, Arteriosclerosis, or ulcerative colitis. Each of the listed diseases is patentably distinct from one another. HIV is different from diabetes type II. Additionally, a search for all the listed populations would impose a

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serious burden on the Examiner. A search for a population that is diagnosed with rheumatoid arthritis would not overlap with a population that is diagnosed with HIV.

b) the composition of the intermediary metabolite: lipids or conjugated biomolecules. Lipids do not have a common utility with conjugated biomolecules nor do lipids have a significant structural similarity as conjugated biomolecules. Hence, lipids are patentably distinct from conjugated biomolecules.

c) the type of cells to be obtained: peripheral blood monocytes (PBMCs), dendritic cells, T cells, stem cells, NK cells, NKT cells, or CD1d cells. Each of the listed type of cells is patentably distinct from one another. T cells differ from those of NK cells and stem cells. Each has a different from in the immune system of a mammalian host.

If Applicant elects Group IV, Applicant must further elect:

a) the type of disease: cancer, viral infection, bacterial infection, or immune dysfunction. If Applicant elects viral infection, Applicant must further elect HBV, HCV, or HIV. If Applicant elects immune dysfunction, Applicant must further elect diabetes type I, diabetes type II, rheumatoid arthritis, Crohn's disease, Arteriosclerosis, or ulcerative colitis. Each of the listed diseases is patentably distinct from one another. HIV is different from diabetes type II. Additionally, a search for all the listed populations would impose a serious burden on the Examiner. A search for a population that is diagnosed with rheumatoid arthritis would not overlap with a population that is diagnosed with HIV.

b) the composition of the intermediary metabolite: lipids or conjugated biomolecules. Lipids do not have a common utility with conjugated biomolecules nor do lipids have a significant structural similarity as conjugated biomolecules. Hence, lipids are patentably distinct from conjugated biomolecules.

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c) the immune stimulating effect achieved by the practice of the claimed method: increasing the intracellular level of the metabolite; increases the rate of production of said mammalian intermediary metabolite; or decreases the rate of degradation or turnover of said mammalian intermediary metabolite. Each of these listed biological activities is patentably distinct from one another. An increase in the serum level of the metabolite is different from an increase in the intracellular and extracellular level of the metabolite or decreases the rate of degradation or turnover of said mammalian intermediary metabolite.

d) the type of cells to be obtained: peripheral blood monocytes (PBMCs), dendritic cells, T cells, stem cells, NK cells, NKT cells, or CD1d cells. Each of the listed type of cells is patentably distinct from one another. T cells differ from those of NK cells and stem cells. Each has a different role from in the immune system of a mammalian host.

If Applicant elects Group V, Applicant must further elect:

a) the type of disease: cancer, viral infection, bacterial infection, or immune dysfunction. If Applicant elects viral infection, Applicant must further elect HBV, HCV, or HIV. If Applicant elects immune dysfunction, Applicant must further elect diabetes type I, diabetes type II, rheumatoid arthritis, Crohn's disease, Arteriosclerosis, or ulcerative colitis. Each of the listed diseases is patentably distinct from one another. HIV is different from diabetes type II. Additionally, a search for all the listed populations would impose a serious burden on the Examiner. A search for a population that is diagnosed with rheumatoid arthritis would not overlap with a population that is diagnosed with HIV.

b) the composition of the intermediary metabolite: lipids or conjugated biomolecules. Lipids do not have a common utility with conjugated biomolecules nor do lipids have a

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significant structural similarity as conjugated biomolecules. Hence, lipids are patentably distinct from conjugated biomolecules.

c) the immune stimulating effect achieved by the practice of the claimed method: modulate or change cellular, humoral, or cytokine elements of the immune system. Each of these listed biological activities is patentably distinct from one another. A modulation or change in the cellular response is different from that of a humoral and cytokine related immune response.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and as shown by their different classification, restriction for examination purposes as indicated is proper. The search required for any of Groups I-V is not required for the other, restriction for examination purposes as indicated is proper.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571) 272 0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*Emily Le*  
E.Le

*James C. Housel*  
JAMES HOUSEL 10/1/04  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600